



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION  
CITY VIEW PLAZA, SUITE 7000  
#48 165 RD. KM 1.2  
GUAYNABO, PR 00968-8069

AUG 1 2017

**CERTIFIED MAIL /RETURN RECEIPT REQUESTED**

**Article Number: 7015 0920 0000 8688 5108**

Mr. Alvin E. Crespo, Director  
Environmental Health and Safety  
Bristol-Myers Squibb Manufacturing Company  
Humacao Operations  
P.O. Box 609  
Humacao, Puerto Rico, 00792-1255

Re: Proposed Contained-In Determination Criteria for the Bristol-Myers Squibb Manufacturing Company,  
Humacao, Puerto Rico  
EPA ID Number: PRD 090021056

Dear Mr. Crespo:

The United States Environmental Protection Agency-Region 2 (EPA) and the Puerto Rico Environmental Quality Board (PREQB) have evaluated your response to EPA comments on the September 7, 2016 proposed contained-in determination criteria and the May 26, 2017 Revised Contained-In Determination Letter for the Bristol-Myers Squibb Manufacturing Company's (BMSMC's) facility in Humacao, Puerto Rico. After thorough review of your responses, EPA considers that BMSMC has adequately addressed most of the comments provided in the EPA letter dated March 24, 2017. However, in the May 26, 2017 Revised Contained-In Determination Letter, BMSMC still maintains that the EPA Regional RMLs are the appropriate health-based levels and rejected using the recommended EPA maximum contaminant levels (MCLs). Moreover, BMSMC has not clarified or identified if it is considering an alternative approach for handling groundwater investigation derived waste (IDW) that could justify the use of RMLs. Consequently, EPA recommends that, in order to accept the use of RMLs, BMSMC shall submit or include a separate IDW Management Plan describing the procedures that will be carried out to justify the use of RMLs. Attached please find PREQB's and EPA's comments on the criteria proposed in your letter.

Please provide your response to all of our comments within 30 days of receipt of this letter. If you have any questions regarding this correspondence, please contact Socorro Martinez of my staff at (787) 977-5886 or via email at [martinez.socorro@epa.gov](mailto:martinez.socorro@epa.gov).

Sincerely,

Carmen R. Guerrero-Pérez  
Director  
Caribbean Environmental Protection Division

cc: Manuel O. Claudio Rodriguez, Manager,  
Land Pollution Control Program, PREQB

Enclosure

## TECHNICAL REVIEW

### RESPONSE TO COMMENTS ON THE PROPOSED CONTAINED-IN DETERMINATION CRITERIA AND REVISED CONTAINED-IN DETERMINATION

#### BRISTOL-MYERS SQUIBB MANUFACTURING COMPANY

#### HUMACAO, PUERTO RICO

## I. INTRODUCTION

On May 22, 2017, BSMC provided response to comments (RTCs) on the proposed contained-in determination criteria and a Revised Contained-In Determination Letter. Most the comments have been adequately addressed, however a few specific concerns remain and are discussed in detail below.

## II. GENERAL COMMENTS

1. **Original EPA Comment:** BSMC's letter does not mention land disposal restrictions (LDR) in the letter. Land disposal restrictions apply to environmental media that contain hazardous waste, and in some instances, will continue to apply even after it has been determined that media no longer contain hazardous waste. If a LDR is applicable, then the proposed contain-in criteria may need to be modified accordingly.

**BSMC Response:** The September 7, 2016 Bristol-Myers Squibb Manufacturing Company (BSMC) letter outlined decision criteria as bases to decide if environmental media destined for treatment and/or off-site disposal contains hazardous waste. BSMC acknowledges that environmental media deemed "contained-out" (i.e., no longer contains hazardous waste) can still be subject to land disposal restrictions (LDRs) if the environmental media destined for land disposal contains underlying hazardous constituents above LDR treatment standards. As such, with this response to the United States Environmental Protection Agency's (EPA's) March 24, 2017 comments, BSMC also submits a revised Contained-In Determination Proposal. This revision acknowledges applicability of LDRs by including alternative treatment standards (ATs equals to ten times the universal treatment standards [UTSs]) for potentially hazardous Constituents of Potential Concern (COPCs) in soil destined for land disposal. At this time, BSMC does not foresee options for land disposal of other environmental media (i.e., groundwater). For each corrective measure, BSMC will characterize and manage remediation waste pursuant to 40 C.F.R § 261 Subpart C in accordance with BSMC Environmental Health and Safety (EH&S) waste management procedures and the revised Contained-In Determination Proposal.

**EPA Comment:** BSMC's response is acceptable.

2. **Original EPA Comment:** BSMC's letter does not address all of the constituents of concern (COCs) for the BSMC Humacao facility. BSMC should document how it established the list of constituents set forth in its table labeled "EPA Health-Based Criteria for the RCRA Contained-In Evaluation," and indicate why known COCs at the facility were eliminated.

**BSMC Response:** BSMC generated the table labeled "EPA Health-Based Criteria for the RCRA Contained-In Evaluation" based on a screening evaluation of the 54 COPCs/COCs detected at the Facility, including: 43 COPCs identified in Table 14 from the February 26, 2016 Release Assessment Report; eight COPCs identified during Phase 1 investigation activities, Phase 2 investigation activities, and/or quarterly groundwater monitoring activities completed following submittal of Table



14 from the February 26, 2016 Release Assessment Report, and three COCs currently addressed under the Facility's Resource Conservation and Recovery Act (RCRA) Hazardous Waste Treatment and Storage Permit (No. PRD090021056) for the Former Tank Farm Area (FTF) and Building 5 Area.

The screening evaluation is based on the EPA's Contained-In Policy<sup>1</sup> (EPA 1998) which indicates that contaminated environmental media, of itself, is not hazardous waste and, generally, is not subject to regulation under the RCRA. Contaminated environmental media can become subject to regulation under RCRA if they "contain" hazardous waste. EPA generally considers contaminated environmental media to contain hazardous waste: (1) when they exhibit a characteristic of hazardous waste; or, (2) when they are contaminated with concentrations of hazardous constituents from listed hazardous waste that are above health-based levels. Accordingly, Table 1 included with the revised Contained-In Determination Proposal summarizes an evaluation of each COPC/COC and shows that 33 of the 54 COPCs/COCs are not subject to the Contained-In Policy based on the following factors:

- the COPC/COC does not exhibit a characteristic of hazardous waste,<sup>2</sup>
- the COPC/COC is not a listed waste,
- the original material was not a waste (e.g., virgin fuel; pesticide applied to soil), and/or
- documentation regarding a source of contamination, contaminant, or waste is unavailable or inconclusive.<sup>3</sup>

As a result, 21 COPCs/COCs are further evaluated under the EPA Contained-In Policy as listed in Table 2 (EPA Health-Based Criteria for the RCRA Contained-In Evaluation) of the revised Contained-In Determination Proposal.

**EPA Comment:** BMSMC's response is partially acceptable. Table 1 incorrectly indicates that 1,2-dichloroethane was not a listed waste when it is a D-listed waste (D028). Please correct Table 1 and add 1,2-dichloroethane to Table 2.

### III. SPECIFIC COMMENTS

3. **Original EPA Comment:** BMSMC proposes using the generic EPA Regional Removal Management Levels for Chemicals (RMLs) for residential tap water and industrial soils. Please, noted that the generic RMLs correspond to risk levels of approximately  $10^{-4}$  and/or a Hazard Quotient of up to 3 for long-term exposure individual chemicals at a site. To be conservative, BMSMC should use the RMLs for residential soils rather than the RMLs for industrial soils for the Contained-In Determination.

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<sup>1</sup> EPA, *Management of Remediation Waste Under RCRA* (EPA530-F-98-026), October 1998

<sup>2</sup> BMSMC acknowledges that it is also required to characterize remediation waste for the other hazardous waste characteristics (i.e., Ignitability, Corrosivity, and Reactivity) pursuant to 40 C.F.R. § 261 Subpart C. In the case of media that exhibit a characteristic of hazardous waste, once the characteristic is eliminated (e.g., through treatment), the media are no longer considered to 'contain' hazardous waste. Since this determination can be made through relatively straightforward analytical testing, no formal 'contained-in' determination by EPA or an authorized state is required." (EPA 1998). Accordingly, constituents that potentially exhibit a characteristic other than Toxicity are not included in Table 2. Nonetheless, all remediation wastes will be characterized pursuant to 40 C.F.R. Part 261 at generation/prior to disposal and any remediation wastes that exhibit a characteristic will either be managed as RCRA hazardous waste and/or treated to eliminate the characteristic.

<sup>3</sup> "Where a facility owner/operator makes a good faith effort to determine if a material is a listed hazardous waste but cannot make such a determination because documentation regarding a source of contamination, contaminant, or waste is unavailable or inconclusive, EPA has stated that one may assume the source, contaminant or waste is not listed hazardous waste and, therefore, provided the material in question does not exhibit a characteristic of hazardous waste, RCRA requirements do not apply" (EPA 1998).

**BMSMC Response:** BMSMC proposed use of industrial-based criteria because BMSMC anticipates that the disposal end point for soil will involve a restricted use (i.e., non-residential) scenario. Although a specific off-site disposal facility has not currently been selected, for each corrective measure, BMSMC will identify a permitted landfill or other appropriately licensed restricted use (i.e., non-residential) disposal facility as part of waste management in accordance with BMSMC EH&S waste management procedures and the revised Contained-In Determination Proposal.

The proposed use of industrial based criteria is consistent with Contained-In Policy Guidance published by States that have been delegated authority from EPA to implement RCRA programs. For example, Wisconsin<sup>4</sup>, Colorado<sup>5</sup>, Oregon<sup>6</sup>, Connecticut<sup>7</sup>, and Indiana<sup>8</sup> policies/guidance include use of nonresidential criteria (or residential criteria increased by an order of magnitude or greater) for establishing contained-in determinations. Moreover, the RMLs provide greater protection relative to EPA's "bright line" concentrations proposed for Hazardous Waste Identification because the RMLs target risk of  $10^{-4}$  for potential carcinogens and a Hazard Quotient (HQ) of 3 for non-carcinogens; whereas, EPA proposed bright line concentrations based on target risk of  $10^{-3}$  for potential carcinogens and a HQ of 10 for non-carcinogens.<sup>9</sup> Accordingly, the revised Contained-In Determination Proposal includes use of RMLs for industrial soils. Please also note that, as identified in the BMSMC response to EPA Comment No. 1, the revised Contained-In Determination Proposal acknowledges applicability of LDRs by including ATSS (ten times the UTSSs) for potentially hazardous COCs/COPCs in soil destined for land disposal.

**EPA Comment:** BMSMC's response is acceptable.

4. **Original EPA Comment:** The Benzene, Methylene Chloride, Tetrachloroethylene RMLs for residential tap water (46 parts per billion (ppb), 320 ppb, 120 ppb respectively) are least an order of magnitude higher than the corresponding maximum contaminant level (all 5 ppb). BMSMC shall use the EPA maximum contaminant levels of 5 ppb.

**BMSMC Response:** BMSMC proposed use of the RMLs to be consistent with EPA Contained-In Policy (EPA 1998) that requires comparison to site-specific health-based levels. As described in the Regional Removal Management Levels (RMLs) User's Guide<sup>10</sup>, generic RMLs are based on default exposure parameters and factors that represent Reasonable Maximum Exposure (RME) conditions for long-term/chronic exposures.

The use of an MCL-based RME for extracted groundwater that assumes direct exposure through daily exposure to tap water over a lifetime is overly conservative. A more plausible exposure mechanism would be potential exposures which could occur after the groundwater is discharged through a publicly-owned treatment works (POTW), which subsequently discharges into a receiving waterbody. Under this exposure approach, the receiving waterbody could be a potential source of potable water.

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4 Wisconsin Department of Natural Resources, *Guidance for Hazardous Waste Remediation*, RR-705, January 2014

5 Colorado Department of Public Health and Environment, *Corrective Action Guidance Document - Appendix 2*, May 2002

6 State of Oregon Department of Environmental Quality, *Conducting Contained-In Determinations for Environmental Media*, February 2015)

7 Connecticut Department of Energy & Environmental Protection, RCRA "Contained-In" Policy, <http://www.ctoov/deep/cwp/view.asp?a=2718&deoNav%20GID=1646&o=325454> accessed 20 April 2017)  
**Updated Link:** <http://www.ct.gov/deep/cwp/view.asp?A=2718&Q=325454>

8 Indiana Department of Environmental Management, *Contained-in Policy Guidance for RCRA*, WASTE-0052, October 2002

9 Bright line concentrations represent a pre-cursor to the current EPA Contained-In Policy Guidance (see <https://archive.epa.gov/epawaste/hazard/web/html/luwirmeffs.html>) and provides context of previous approaches to hazardous waste identification for contaminated media proposed by EPA.

10 EPA, <https://www.epa.gov/risk/regional-removal-management-levels-rmls-users-guide>, accessed on 20 April 2017.



For example, a potential management alternative for extracted groundwater involves discharge to the Humacao Regional Wastewater Treatment Plant (HRWWTP), subject to BMSMC securing approval of the POTW operator (Puerto Rico Aqueduct and Sewer Authority [PRASA]<sup>11</sup>). The HRWWTP discharges to the Atlantic Ocean which is not used as a source of drinking water. Although a specific off-site disposal facility for extracted groundwater has not currently been selected, for each corrective measure, BMSMC will identify a permitted POTW or other appropriately permitted facility as part of waste management in accordance with BMSMC EH&S waste management procedures and the revised Contained-In Determination Proposal.

**EPA Comment:** BMSMC has not adequately assessed this comment. Specifically:

- a. Although MCLs and RMLs are derived in a different manner, both the MCLs and RMLs are health-based levels. Until BMSMC proposes a revised approach for addressing groundwater IDW, EPA will not be able to evaluate whether BMSMC's proposal to use the RMLs as an alternative to the EPA MCLs is appropriate.
  - b. The Release Assessment Work Plans submitted to date state: "Liquid Investigation Derived Waste (IDW) will also be managed and disposed of as hazardous waste. Liquid IDW will be collected in the facility's RCRA Hazardous Waste Storage Tank, T-901. BMSMC will dispose the contents of T-901 as hazardous waste at an offsite RCRA permitted hazardous waste disposal facility in accordance with BMSMC's RCRA Hazardous Waste Management Permit." If BMSMC is now proposing an alternative IDW management approach, a IDW management plan independent of this Contained-In Determination Letter should be submitted to EPA and PREQB for review.
  - c. If BMSMC is proposing that acceptance criteria or pretreatment criteria for a permitted POTW or other permitted facility be used as "Contained-Out" criteria, BMSMC should provide these criteria to EPA and PREQB for review and concurrence. Until BMSMC demonstrates there is a POTW or other permitted facility that can accept their groundwater IDW, the EPA MCLs are the appropriate "Contained-Out" criteria for the COPCs that have EPA MCLs.
5. **Original EPA Comment:** BMSMC is proposing to use the RCRA toxicity criteria even though the RMLs for residential are lower. BMSMC shall use the RMLs for residential soils.

**BMSMC Response:** BMSMC proposed to use the RCRA toxicity criteria for identifying if waste is hazardous based on the toxicity characteristic. It is important to note that 1) the toxicity characteristic is defined by federal rules (not guidance) and, therefore, 2) in accordance with EPA's Contained-In Policy (EPA 1998), BMSMC is not required to seek approval from EPA or Puerto Rico Environmental Quality Board (PREQB) for its Contained-In Determination for characteristic wastes:

"In the case of media that exhibit a characteristic of hazardous waste, the media are considered to 'contain' hazardous waste for as long as they exhibit a characteristic. Once the characteristic is eliminated (e.g., through treatment), the media are no longer considered to 'contain' hazardous waste. Since this determination can be made through relatively straightforward analytical testing, no formal 'contained-in' determination by EPA or an authorized state is required." (EPA 1998)

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<sup>11</sup> Securing this approval would involve a comparison of COC/COPC concentrations in extracted groundwater to POTW-specific pretreatment standards and/or POTW acceptance criteria that contemplate designated uses of the receiving waterbody.

Additionally, and consistent with the above response to EPA Comment No. 3, BMSMC proposes to use the industrial RMLs for making contained-in determinations for soil with listed COCs/COPCs.

**EPA Comment:** BMSMC's response is acceptable.

6. **Original EPA Comment:** The Benzyl Chloride RML for residential tap water is 5.9 ppb and not 6 ppb.

**BMSMC Response:** The revised Contained-In Determination Proposal reflects the Benzyl Chloride RML of 5.9 ppb.

**EPA Comment:** BMSMC's response is acceptable.

7. **Original EPA Comment:** The Tetrahydrofuran RML for industrial soils is 280,000 mg/kg, but the EPA Health-Based Criteria for RCRA Contained-In Evaluation Table lists 105,000 mg/kg for Tetrahydrofuran. This latter number should be used.

**BMSMC Response:** BMSMC acknowledges that the EPA Health-Based Criteria for RCRA Contained-In Evaluation Table incorrectly identifies the Tetrahydrofuran RML at 105,000 mg/kg. Accordingly, no basis exists for establishing the Tetrahydrofuran Contained-In criteria at 105,000 mg/kg. However, the revised Contained-In Determination Proposal continues to use the lower (i.e., incorrect) Tetrahydrofuran criteria in response to this EPA comment.

**EPA Comment:** BMSMC's response is acceptable.

8. **Original EPA Comment:** EPA Health-Based Criteria for RCRA Contained-In Evaluation Table categorized constituents into Potential Carcinogens (Oral Exposure) or Non-Carcinogens (Oral Exposure). These categories are misleading because some of the RMLs are based on combined pathways or other RMLs are based on carcinogenic target risk for the groundwater but non-carcinogenic hazard index for soils. These categories should therefore be removed from this table.

**BMSMC Response:** BMSMC revised the Contained-In Determination Proposal in response to this comment. As requested by EPA, the EPA Health-Based Criteria for RCRA Contained-In Evaluation Table included with the revised Contained-In Determination Proposal no longer contains Potential Carcinogen (Oral Exposure) and Non-Carcinogen (Oral Exposure) categories.

**EPA Comment:** BMSMC's response is acceptable.

#### IV. PREQB COMMENTS

9. **Original PREQB Comment:** It is recommended to characterize the waste as per 40 CFR Part 261.

**BMSMC Response:** The 7 September 2016 BMSMC letter outlined decision criteria as bases to decide if environmental media destined for treatment and/or off-site disposal contains hazardous waste. BMSMC acknowledges that remediation waste must be characterized in accordance with 40 CFR Part 261 upon generation/prior to treatment and/or off-site disposal. Accordingly, for each corrective measure, BMSMC will characterize and manage remediation waste pursuant to 40 C.F.R. § 261 Subpart C in accordance with BMSMC EH&S waste management procedures and the revised Contained-In Determination Proposal.

**EPA Comment:** BMSMC has adequately addressed PREQB's comment.

10. **Original PREQB Comment:** The letter indicates that the proposed action does not considered the treatment and disposal end points, only management as part of the corrective action activities. Please



provide how the wastes will be managed during the project implementation. The EPA's guidance EPA530-F-98-026 Management of Remediation Waste Under RCRA recommends that even when contaminated media has been treated and determination that it no longer contains hazardous wastes, the media could still be subject to Land Disposal Restrictions.

**BMSMC Response:** The 7 September 2016 BMSMC letter outlined decision criteria as bases to decide if environmental media destined for treatment and/or off-site disposal contains hazardous waste. BMSMC acknowledges that remediation waste must be characterized in accordance with 40 CFR Part 261 upon generation/ prior to treatment and/or off-site disposal. BMSMC has not currently identified specific off-site disposal facilities for remediation waste management. Accordingly, for each corrective measure, BMSMC will characterize and manage remediation waste pursuant to 40 C.F.R. § 261 Subpart C in accordance with BMSMC EH&S waste management procedures and the revised Contained-In Determination Proposal. Additionally, as indicated in BMSMC response to EPA Comment No. 1 above, the revised Contained-In Determination Proposal acknowledges that environmental media deemed "contained-out" (i.e., no longer contains hazardous waste) can still be subject to LDRs.

**EPA Comment:** BMSMC has adequately addressed PREQB's comment.

11. **Original PREQB Comment:** The letter does not include any sampling description to ensure that a characteristic sample will be taken. The frequency of sampling should also be provided.

**BMSMC Response:** The 7 September 2016 BMSMC letter outlined decision criteria as bases to decide if environmental media destined for treatment and/or off-site disposal contains hazardous waste. BMSMC acknowledges that remediation waste must be characterized in accordance with 40 CFR Part 261 upon generation/prior to treatment and/or off-site disposal. Accordingly, for each corrective measure, BMSMC will characterize and manage remediation waste pursuant to 40 C.F.R. § 261 Subpart C in accordance with BMSMC EH&S waste management procedures and the revised Contained-In Determination Proposal.

**EPA Comment:** BMSMC has partially addressed. BMSMC has not addressed the concerns regarding frequency of sampling. As indicated above, if BMSMC is now proposing an alternative IDW management approach other than the approach presented in the Release Assessment Work Plans, an IDW management plan independent of this Contained-In Determination Letter should be submitted to EPA and PREQB for review.

## V. NEW EPA COMMENTS

12. **EPA Comment:** Table 2 presents the EPA Health-Based Criteria for RCRA Contained-In information and uses shading, “^” symbol, or “\*” symbol to identify which value is being used in lieu of the EPA Regional Removal Management Levels (RML). However this approach is difficult to follow. For clarity, it is recommended that all the EPA Regional RMLs for Tap Water and Industrial Soil be listed on this table and two additional columns be added to the table which identify the pertinent hazardous waste levels in soil and groundwater for each constituent.

June 26, 2017  
REPA5-4205-0123

Ms. Patricia Rosa  
Contracting Officer  
U.S. EPA Region 2  
290 Broadway, 22<sup>nd</sup> Floor  
New York, NY 10007-1966

Re: Contract No. EP-BPA-12-W-0005  
RCRA Enforcement, Permitting, and Assistance Contract, REPA5, Region 2

Subject: Task Order No. 005, Technical Review of the Revised Contained-In Determination for  
Bristol-Myers Squibb Manufacturing Company, Humacao, Puerto Rico Facility, EPA ID  
No. PRD090021056

Dear Ms. Rosa:

In response to Task Order No. 005, under Contract No. EP-BPA-12-W-0005, Booz Allen Hamilton (Booz Allen) is pleased to submit our technical review of Bristol-Myers Squibb Manufacturing Company's (BMSMC's) response to comments (RTCs) on the proposed contained-in determination criteria and the May 26, 2017 Revised Contained-In Determination Letter for the BMSMC facility in Humacao, Puerto Rico.

Our review of this letter indicates that BMSMC has adequately addressed most of the comments. Previously, EPA commented that maximum contaminant level (all 5 ppb) for benzene, methylene chloride, tetrachloroethylene should be used instead of the EPA Regional Removal Management Levels (RMLs) for residential tap water (46 parts per billion (ppb), 320 ppb, and 120 ppb respectively). BMSMC maintains however that the EPA Regional RMLs are appropriate health-based levels and rejected using the EPA maximum contaminant levels (MCLs) in their response to comments. Additionally, BMSMC has not yet identified an alternative approach for handling groundwater investigation derived waste (IDW) and so it is unclear how BMSMC intends to treat or dispose of groundwater IDW that contains constituents above EPA MCLs and where the Clean Water Act regulations may also apply. Thus, it is recommended that BMSMC present a separate IDW Management Plan to EPA before EPA approves BMSMC's request to use the EPA Regional RML in lieu of the EPA MCLs. This concern along with a few other minor issues are discussed in the attached deliverable.

If you have any questions on this deliverable, please contact me at (919) 462-9004.

Sincerely,

*Connie Crossley*

BOOZ ALLEN HAMILTON, INC.

Connie Crossley

Task Order Manager

Enclosure

cc: Derek Davis, EPA Contracting Officer  
Luis Negrón, EPA TOCOR  
Socorro Martinez, EPA Caribbean Office



## TECHNICAL REVIEW

### RESPONSE TO COMMENTS ON THE PROPOSED CONTAINED-IN DETERMINATION CRITERIA AND REVISED CONTAINED-IN DETERMINATION

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<sup>3</sup> "Where a facility owner/operator makes a good faith effort to determine if a material is a listed hazardous waste but cannot make such a determination because documentation regarding a source of contamination, contaminant, or waste is unavailable or inconclusive, EPA has stated that one may assume the source, contaminant or waste is not listed hazardous waste and, therefore, provided the material in question does not exhibit a characteristic of hazardous waste, RCRA requirements do not apply" (EPA 1998).



**BMSMC Response:** BMSMC proposed use of industrial-based criteria because BMSMC anticipates that the disposal end point for soil will involve a restricted use (i.e., non-residential) scenario. Although a specific off-site disposal facility has not currently been selected, for each corrective measure, BMSMC will identify a permitted landfill or other appropriately licensed restricted use (i.e., non-residential) disposal facility as part of waste management in accordance with BMSMC EH&S waste management procedures and the revised Contained-In Determination Proposal.

The proposed use of industrial based criteria is consistent with Contained-In Policy Guidance published by States that have been delegated authority from EPA to implement RCRA programs. For example, Wisconsin<sup>4</sup>, Colorado<sup>5</sup>, Oregon<sup>6</sup>, Connecticut<sup>7</sup>, and Indiana<sup>8</sup> policies/guidance include use of nonresidential criteria (or residential criteria increased by an order of magnitude or greater) for establishing contained-in determinations. Moreover, the RMLs provide greater protection relative to EPA's "bright line" concentrations proposed for Hazardous Waste Identification because the RMLs target risk of  $10^{-4}$  for potential carcinogens and a Hazard Quotient (HQ) of 3 for non-carcinogens; whereas, EPA proposed bright line concentrations based on target risk of  $10^{-3}$  for potential carcinogens and a HQ of 10 for non-carcinogens.<sup>9</sup> Accordingly, the revised Contained-In Determination Proposal includes use of RMLs for industrial soils. Please also note that, as identified in the BMSMC response to EPA Comment No. 1, the revised Contained-In Determination Proposal acknowledges applicability of LDRs by including ATs (ten times the UTs) for potentially hazardous COCs/COPCs in soil destined for land disposal.

**EPA Comment:** BMSMC's response is acceptable.

4. **Original EPA Comment:** The Benzene, Methylene Chloride, Tetrachloroethylene RMLs for residential tap water (46 parts per billion (ppb), 320 ppb, 120 ppb respectively) are least an order of magnitude higher than the corresponding maximum contaminant level (all 5 ppb). BMSMC shall use the EPA maximum contaminant levels of 5 ppb.

**BMSMC Response:** BMSMC proposed use of the RMLs to be consistent with EPA Contained-In Policy (EPA 1998) that requires comparison to site-specific health-based levels. As described in the Regional Removal Management Levels (RMLs) User's Guide<sup>10</sup>, generic RMLs are based on default exposure parameters and factors that represent Reasonable Maximum Exposure (RME) conditions for long-term/chronic exposures.

The use of an MCL-based RME for extracted groundwater that assumes direct exposure through daily exposure to tap water over a lifetime is overly conservative. A more plausible exposure mechanism would be potential exposures which could occur after the groundwater is discharged through a publicly-owned treatment works (POTW), which subsequently discharges into a receiving waterbody. Under this exposure approach, the receiving waterbody could be a potential source of potable water.

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<sup>4</sup> Wisconsin Department of Natural Resources, *Guidance for Hazardous Waste Remediation*, RR-705, January 2014

<sup>5</sup> Colorado Department of Public Health and Environment, *Corrective Action Guidance Document - Appendix 2*, May 2002

<sup>6</sup> State of Oregon Department of Environmental Quality, *Conducting Contained-In Determinations for Environmental Media*, February 2015)

<sup>7</sup> Connecticut Department of Energy & Environmental Protection, RCRA "Contained-In" Policy, <http://www.ctoov/deep/cwp/view.asp?a=2718&deoNav GID=1646&o=325454> accessed 20 April 2017)  
**Updated Link:** <http://www.ct.gov/deep/cwp/view.asp?A=2718&Q=325454>

<sup>8</sup> Indiana Department of Environmental Management, *Contained-in Policy Guidance for RCRA*, WASTE-0052, October 2002

<sup>9</sup> Bright line concentrations represent a pre-cursor to the current EPA Contained-In Policy Guidance (see <https://archive.epa.gov/epawaste/hazard/web/html/iwirmefs.html>) and provides context of previous approaches to hazardous waste identification for contaminated media proposed by EPA.

<sup>10</sup> EPA, <https://www.epa.gov/risk/regional-removal-management-levels-rmls-users-guide>, accessed on 20 April 2017.

For example, a potential management alternative for extracted groundwater involves discharge to the Humacao Regional Wastewater Treatment Plant (HRWWTP), subject to BMSMC securing approval of the POTW operator (Puerto Rico Aqueduct and Sewer Authority [PRASA]<sup>11</sup>). The HRWWTP discharges to the Atlantic Ocean which is not used as a source of drinking water. Although a specific off-site disposal facility for extracted groundwater has not currently been selected, for each corrective measure, BMSMC will identify a permitted POTW or other appropriately permitted facility as part of waste management in accordance with BMSMC EH&S waste management procedures and the revised Contained-In Determination Proposal.

**EPA Comment:** BMSMC has not adequately assessed this comment. Specifically:

- a. Although MCLs and RMLs are derived in a different manner, both the MCLs and RMLs are health-based levels. Until BMSMC proposes a revised approach for addressing groundwater IDW, EPA will not be able to evaluate whether BMSMC's proposal to use the RMLs as an alternative to the EPA MCLs is appropriate.
- b. The Release Assessment Work Plans submitted to date state: "Liquid Investigation Derived Waste (IDW) will also be managed and disposed of as hazardous waste. Liquid IDW will be collected in the facility's RCRA Hazardous Waste Storage Tank, T-901. BMSMC will dispose the contents of T-901 as hazardous waste at an offsite RCRA permitted hazardous waste disposal facility in accordance with BMSMC's RCRA Hazardous Waste Management Permit." If BMSMC is now proposing an alternative IDW management approach, a IDW management plan independent of this Contained-In Determination Letter should be submitted to EPA and PREQB for review.
- c. If BMSMC is proposing that acceptance criteria or pretreatment criteria for a permitted POTW or other permitted facility be used as "Contained-Out" criteria, BMSMC should provide these criteria to EPA and PREQB for review and concurrence. Until BMSMC demonstrates there is a POTW or other permitted facility that can accept their groundwater IDW, the EPA MCLs are the appropriate "Contained-Out" criteria for the COPCs that have EPA MCLs.

5. **Original EPA Comment:** BMSMC is proposing to use the RCRA toxicity criteria even though the RMLs for residential are lower. BMSMC shall use the RMLs for residential soils.

**BMSMC Response:** BMSMC proposed to use the RCRA toxicity criteria for identifying if waste is hazardous based on the toxicity characteristic. It is important to note that 1) the toxicity characteristic is defined by federal rules (not guidance) and, therefore, 2) in accordance with EPA's Contained-In Policy (EPA 1998), BMSMC is not required to seek approval from EPA or Puerto Rico Environmental Quality Board (PREQB) for its Contained-In Determination for characteristic wastes:

"In the case of media that exhibit a characteristic of hazardous waste, the media are considered to 'contain' hazardous waste for as long as they exhibit a characteristic. Once the characteristic is eliminated (e.g., through treatment), the media are no longer considered to 'contain' hazardous waste. Since this determination can be made through relatively straightforward analytical testing, no formal 'contained-in' determination by EPA or an authorized state is required." (EPA 1998)

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<sup>11</sup> *Securing this approval would involve a comparison of COC/COPC concentrations in extracted groundwater to POTW-specific pretreatment standards and/or POTW acceptance criteria that contemplate designated uses of the receiving waterbody.*



Additionally, and consistent with the above response to EPA Comment No. 3, BMSMC proposes to use the industrial RMLs for making contained-in determinations for soil with listed COCs/COPCs.

**EPA Comment:** BMSMC's response is acceptable.

6. **Original EPA Comment:** The Benzyl Chloride RML for residential tap water is 5.9 ppb and not 6 ppb.

**BMSMC Response:** The revised Contained-In Determination Proposal reflects the Benzyl Chloride RML of 5.9 ppb.

**EPA Comment:** BMSMC's response is acceptable.

7. **Original EPA Comment:** The Tetrahydrofuran RML for industrial soils is 280,000 mg/kg, but the EPA Health-Based Criteria for RCRA Contained-In Evaluation Table lists 105,000 mg/kg for Tetrahydrofuran. This latter number should be used.

**BMSMC Response:** BMSMC acknowledges that the EPA Health-Based Criteria for RCRA Contained-In Evaluation Table incorrectly identifies the Tetrahydrofuran RML at 105,000 mg/kg. Accordingly, no basis exists for establishing the Tetrahydrofuran Contained-In criteria at 105,000 mg/kg. However, the revised Contained-In Determination Proposal continues to use the lower (i.e., incorrect) Tetrahydrofuran criteria in response to this EPA comment.

**EPA Comment:** BMSMC's response is acceptable.

8. **Original EPA Comment:** EPA Health-Based Criteria for RCRA Contained-In Evaluation Table categorized constituents into Potential Carcinogens (Oral Exposure) or Non-Carcinogens (Oral Exposure). These categories are misleading because some of the RMLs are based on combined pathways or other RMLs are based on carcinogenic target risk for the groundwater but non-carcinogenic hazard index for soils. These categories should therefore be removed from this table.

**BMSMC Response:** BMSMC revised the Contained-In Determination Proposal in response to this comment. As requested by EPA, the EPA Health-Based Criteria for RCRA Contained-In Evaluation Table included with the revised Contained-In Determination Proposal no longer contains Potential Carcinogen (Oral Exposure) and Non-Carcinogen (Oral Exposure) categories.

**EPA Comment:** BMSMC's response is acceptable.

#### IV. PREQB COMMENTS

9. **Original PREQB Comment:** It is recommended to characterize the waste as per 40 CFR Part 261.

**BMSMC Response:** The 7 September 2016 BMSMC letter outlined decision criteria as bases to decide if environmental media destined for treatment and/or off-site disposal contains hazardous waste. BMSMC acknowledges that remediation waste must be characterized in accordance with 40 CFR Part 261 upon generation/prior to treatment and/or off-site disposal. Accordingly, for each corrective measure, BMSMC will characterize and manage remediation waste pursuant to 40 C.F.R. § 261 Subpart C in accordance with BMSMC EH&S waste management procedures and the revised Contained-In Determination Proposal.

**EPA Comment:** BMSMC has adequately addressed PREQB's comment.

10. **Original PREQB Comment:** The letter indicates that the proposed action does not considered the treatment and disposal end points, only management as part of the corrective action activities. Please

provide how the wastes will be managed during the project implementation. The EPA's guidance EPA530-F-98-026 Management of Remediation Waste Under RCRA recommends that even when contaminated media has been treated and determination that it no longer contains hazardous wastes, the media could still be subject to Land Disposal Restrictions.

**BMSMC Response:** The 7 September 2016 BMSMC letter outlined decision criteria as bases to decide if environmental media destined for treatment and/or off-site disposal contains hazardous waste. BMSMC acknowledges that remediation waste must be characterized in accordance with 40 CFR Part 261 upon generation/ prior to treatment and/or off-site disposal. BMSMC has not currently identified specific off-site disposal facilities for remediation waste management. Accordingly, for each corrective measure, BMSMC will characterize and manage remediation waste pursuant to 40 C.F.R. § 261 Subpart C in accordance with BMSMC EH&S waste management procedures and the revised Contained-In Determination Proposal. Additionally, as indicated in BMSMC response to EPA Comment No. 1 above, the revised Contained-In Determination Proposal acknowledges that environmental media deemed "contained-out" (i.e., no longer contains hazardous waste) can still be subject to LDRs.

**EPA Comment:** BMSMC has adequately addressed PREQB's comment.

11. **Original PREQB Comment:** The letter does not include any sampling description to ensure that a characteristic sample will be taken. The frequency of sampling should also be provided.

**BMSMC Response:** The 7 September 2016 BMSMC letter outlined decision criteria as bases to decide if environmental media destined for treatment and/or off-site disposal contains hazardous waste. BMSMC acknowledges that remediation waste must be characterized in accordance with 40 CFR Part 261 upon generation/prior to treatment and/or off-site disposal. Accordingly, for each corrective measure, BMSMC will characterize and manage remediation waste pursuant to 40 C.F.R. § 261 Subpart C in accordance with BMSMC EH&S waste management procedures and the revised Contained-In Determination Proposal.

**EPA Comment:** BMSMC has partially addressed. BMSMC has not addressed the concerns regarding frequency of sampling. As indicated above, if BMSMC is now proposing an alternative IDW management approach other than the approach presented in the Release Assessment Work Plans, an IDW management plan independent of this Contained-In Determination Letter should be submitted to EPA and PREQB for review.

## V. NEW EPA COMMENTS

12. **EPA Comment:** Table 2 presents the EPA Health-Based Criteria for RCRA Contained-In information and uses shading, “^” symbol, or “\*” symbol to identify which value is being used in lieu of the EPA Regional Removal Management Levels (RML). However this approach is difficult to follow. For clarity, it is recommended that all the EPA Regional RMLs for Tap Water and Industrial Soil be listed on this table and two additional columns be added to the table which identify the pertinent hazardous waste levels in soil and groundwater for each constituent.